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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/598,852

06/20/2000

Kenneth H. Mollenauer

212/262

7145

23371

7590

12/23/2003

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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/598,852

Applicant(s)

MOLLENAUER, KENNETH H.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

R sponse to Am ndm nt

The rejection applied under Ramsey, III is being maintained with respect to claims 1-5 and 9-10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5,9-10, 14-16,17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramsey, III (6,148,222).

Ramsey, III discloses a device having a catheter body, a first and second balloon located at the distal end of the catheter, a first and second heating element (20) and wires (19). See figures 1- 7 . Specifically , fig. 5 shows

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a plurality of balloons, plurality of suction lumens and plurality of heating element and wires. See fig. 6 and 7 at heating elements (20 a and 20b). It is inherent that there is a vacuum source operably connected to the suction lumen.

Ramsey, III discloses that ports 18 may function as aspiration ports. See col. 4, line 24-26. With respect to applicant's functional limitation of the first and second heating element capable of delivering sufficient energy to the tissue to shrink the tissue, applicant is reminded that applicant has a device claim and lacking any structurally distinguishing features the Examiner is maintaining that Ramsey, III 's device is capable of performing the intended use. Ramsey, III discloses the a power source 25 connected to the heating elements. See col. 2, line 44-45, col. 3, line 19-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey, III (6,148,222).in view of McGovern et al. (U.S. Patent No. 6,517,534).

Ramsey, III discloses the invention as substantially claimed. See above. However, Ramsey, III does not disclose a resistive heating element (s).

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McGovern et al. disclose heating elements can be resistive heating elements or electrodes, which are alternatives. See col. 6, lines 5-10. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the electrode of Ramsey, III for the resistive heating elements of McGovern et al. as a mere substitute of parts.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey, III (6,148,222)

Ramsey, III discloses the invention as substantially claimed. Ramsey, III discloses a power supply. However, Ramsey, III is silent to a DC power source. DC power sources are well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute or modify the power source of Ramsey, III for a DC power source in order to provide power for the heating element.

Response to Arguments

Applicant's arguments filed 10/08/03 have been fully considered but they are not persuasive.

With respect to the heating element, Ramsey et al. does teach heating elements being considered by the Examiner as the electrodes. Ramsey, III, does avoids burns but the claimed limitation is for a heating element, and it is still considered to be a heating element since there is an electrical current which passes through the electrodes, wherein heat would be existent.

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Applicant is reminded that the claims are directed to a device and without distinguishing structural limitations the prior art of record still anticipates the claim. The intended use imposes no limitation to the claim in the absence of structurally distinguishing features.

In response to applicant's argument that the heating elements are capable of delivering sufficient energy to the tissue to shrink the tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

With respect to the limitation of the vacuum source coupled to the suction lumen, it is considered to be inherent. Applicant is directed to the col. 4, lines 24-26. Ramsey, III discloses liquid is withdrawn from the esophagus at the termination of the therapeutic procedure through the port and flow lumen. It is very well recognized by one of ordinary skill in the art that fluid to be withdrawn has to be performed by a negative source. Thus, it is inherent that a vacuum source would be operably connected to the "suction" lumen. Since Ramsey discloses using the port to remove fluid through the port and lumen, it could be further construed that the lumen is a suction lumen. (Just a given name to a lumen). Ramsey does not physically show a drawing of a vacuum, however, he

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teaches that the device functions to withdraw fluid. The Examiner maintains that the vacuum source is inherent. It is well within the knowledge of one of ordinary skill in the art. Applicant's suggestion of tilting the patient in absence of a vacuum is not reasonable to one of ordinary skill in the art since it would not be consistently advantageous to tilt the patient. Applicant has not claimed any structurally distinguishing features that would overcome Ramsey, III. Functional language is given minimal patentable weight in a device claim and as such the Examiner is maintaining that the device of Ramsey, III is capable of performing the function as claimed.

With respect to the heating element, Ramsey et al. does teach heating elements being considered by the Examiner as the electrodes. Ramsey, III, does avoid burns but the claimed limitation is for a heating element, and it is still considered to be a heating element since there is an electrical current which passes through the electrodes, wherein heat would be existent.

Applicant is reminded that the claims are directed to a device and without distinguishing structural limitations the prior art of record still anticipates the claim. The intended use imposes no limitation to the claim in the absence of structurally distinguishing features.

In response to applicant's argument that the heating elements are capable of delivering sufficient energy to the tissue to shrink the tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

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capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

With respect to applicant's contention that not enough heat is produced by Ramsey to shrink the tissue, it is considered to be capable of performing the intended use. Applicant has broadly claimed "sufficient heat" and as such, the Examiner is interpreting broadly as well since there is no degree of how much is sufficient and to what tissue and how long it would take to shrink the tissue.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will


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the statutory period for reply expire later than SIX MONTHS from the date of this final action. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on Mon-Fri (alternate Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT